REMARKS

The present invention relates to compositions and methods for the use of insulin-like growth factor to enhance muscle mass and strength.

Claims 1-18 and 23 are under consideration, claims 19-22 having been withdrawn from consideration as being drawn to a non-elected invention.

Claims 1, 7, 8, and 9 have been amended herein. Support for these amendments is found throughout the specification as filed and as more fully set forth below. Therefore, no new matter has been added by way of these amendments.

Claim 24 has been added herein. Claim 24 is amply supported by the specification as filed and introduces no new subject matter. Two forms of IGF-1 precursor polypeptides can be formed by alternative RNA processing. The specification discloses that both forms work in the present invention and claim 24 merely recites this discovery. Support for this newly added claim is found throughout the specification, particularly at page 12, lines 8-10.

Rejection of claims 1-18 and 23 pursuant to 35 U.S.C. § 112, first paragraph

Claims 1-18 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, because in the view of the Examiner, they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that at the time the application was filed the Applicants had possession of the claimed invention.

Specifically, the Examiner asserts that Applicants do not provide a written description of a modified IGF-1 coding region or a portion of the region that will produce the claimed effects. Although not necessarily agreeing with the reasoning of the Examiner, in a good faith effort to expedite prosecution of the application, Applicants have amended the two independent claims which recite the phrases referred to by the Examiner. Namely, Applicants have amended the claims by deleting the phrase "or a modification or biologically active portion thereof" in claim 1 and by deleting the phrase "or a modification or portion thereof" in claim 7.

Applicants respectfully submit that this amendment does not exclude the two forms of IGF-1 precursor polypeptides which can be derived by alternative RNA processing, because both forms of polypeptide are described in the specification at page 12, lines 8-10 as being IGF-1. This amendment introduces no new subject matter.

Applicants request that the rejection of claims 1-18 and 23 be reconsidered and withdrawn.

Rejection of claims 1-6, 8-10, 13, 14, 15, 17, and 23 pursuant to 35 U.S.C. § 112, second paragraph

Claims 1-6, 8-10, 13, 14, 15, 17, and 23 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

More specifically, the Examiner contends that the claims are indefinite in their recitation of: "the muscle" (claims 1-6 and 23) because, the term lacks antecedent basis; "selected from a group consisting of" (claims 8-10), because the phrasing is improper Markush terminology; "[t]he method of Claim 8" (claim 9), because claim 8 is directed to an isolated nucleic acid, not a method; and "said isolated nucleic acid of claim 12" (claims 13, 14, 15, and 17), because the phrase lacks antecedent basis.

Applicants, while not necessarily agreeing with the Examiner's reasoning, in a good faith effort to expedite prosecution of the application have amended claims 1, 8, and 9.

Claim 1 has been amended to remove the phrase "the muscle". Claim 8 has been amended such that the phrase "selected from a group consisting of" has been replaced with the phrase "selected from the group consisting of". Claim 9 has been amended such that the phrase "[t]he method of claim 8" has been replaced with the phrase "[t]he isolated nucleic acid of claim 8".

Claim 13 stands rejected as being indefinite because it is the Examiner's view that recitation of "said isolated nucleic acid of claim 12" lacks antecedent basis. Applicants do not understand the reasoning of the Examiner and respectfully traverse this rejection. Claim 13 properly depends from claim 12, which recites "the isolated nucleic of claim 11". Claim 11, properly depends from claim 7, an independent claim reciting "an isolated nucleic acid". Applicants respectfully request that this rejection be reconsidered and withdrawn.

Applicants respectfully submit that rejection of claims 1-6, 8-10, 13, 14, 15, and 17 under 35 U.S.C. § 112, second paragraph has been overcome or is now inapplicable and that each claim is in condition for allowance. Thus, Applicants respectfully request that this rejection be reconsidered and withdrawn.

New claim 24, as added herein, is amply supported by the specification as filed (for example, see page 12, lines 8-10), as more fully set forth above.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that each of currently pending claims 1-18, and 23, as well as newly added claim 24, is in condition for allowance. Reconsideration and allowance of claims 1-18 and 23 and 24 are respectfully requested at the earliest possible date.

Respectfully submitted,
H. LEE SWEENEY *ET AL.*

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KATHRYN DOYLE, PhD., J.D.
Registration No. 36,317
MORGAN, LEWIS & BOCKIUS, LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Direct Dial: (215) 963-4723
Facsimile: (215) 963-5299
E-Mail: kdoyle@morganlewis.com
Attorney for Applicants

KD/RLS/prw
Enclosures (petition for one-month extension of time and fee therefor; amendment cover sheet; fee for additional dependent claim; "marked-up" copy of the claims)

Marked-up Claims Responsive to Office Action August 28, 2001 (Paper No. 8)

1. (Amended) A method of increasing vertebrate muscle mass and muscle strength, said method comprising administering a muscle enhancing dose of an isolated nucleic acid encoding Insulin-like Growth Factor I (IGF-I)[, or a modification or biologically active portion thereof,] intramuscularly into a vertebrate, wherein said isolated nucleic acid is expressed in muscle cells, thereby increasing said muscle mass and said muscle strength in [the muscle of] said vertebrate.

7. (Amended) An isolated nucleic acid comprising a vertebrate Insulin-like Growth Factor I (IGF-1) coding region, [or a modification or portion thereof,] operably linked to a muscle specific promoter/regulatory region, wherein said IGF-1 coding region is flanked on the 5' side by an SV40 intron sequence and wherein said IGF-1 coding region is flanked on the 3' end by an SV40 polyadenylation signal sequence.

8. (Amended) The isolated nucleic acid of claim 7, wherein said muscle specific promoter/regulatory region is selected from [a] the group consisting of the myosin light chain 1/3 promoter/enhancer, the skeletal α-actin promoter, the muscle creatine kinase promoter/enhancer and a muscle specific troponin promoter.

9. (Amended) [The method] The isolated nucleic acid of claim 8, wherein said muscle specific troponin promoter is the fast troponin C promoter/enhancer.